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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/533,833 | 05/03/2005 | Masahiro Kajino | Q101061 | 7356 |

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| EXAMINER | |
|---|---|
| MABRY, JOHN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1625 | |

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|---|---|
| 03/18/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/533,833 | KAJINO ET AL. | |
| | Examiner | Art Unit | |
| | John Mabry, PhD | 1625 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *5/03/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9 and 11-28* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) *1-9 and 11-28* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objection*

Applicant is advised that claim 10 is a "Use" claims. Please see MPEP 2173.05(q) for information on "use" claims. "Use" claim has been withdrawn from examination.

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11-26 and 28 are drawn to compounds of Formula B, wherein Q2=-COR2 where R2 is unsubstituted alkyl, haloalkyl, unsubstituted alkoxy, phenyl; Y=phenyl substituted with H, unsubstituted alkyl, halogen; Xb=piperidinyl substituted at the N-terminal with –Z-A where –Z- is unsubstituted methylene (-CH2-) or substituted with unsubstituted alkyl and –A is phenyl substituted with H, alkyl, halogen, alkoxy, haloalkylalkoxy, -S alkyl, -NHalkyl, and R1 (of Xb)= pyridinyl substituted with H, thienyl, -Salkyl, halogen and alkyl; thiazolyl substituted with H and alkyl; cyano; -CO2alkyl substituted with H, alkyl, phenyl; and imidazolyl and compositions thereof classified in class 546, subclass 194 and class 514, subclass 317. A further election of a single disclosed species is required.

II. Claims 1-8, 11-26 and 28 are drawn to compounds of Formula B, wherein Q2=-COR2 where R2 is unsubstituted alkyl, haloalkyl, unsubstituted alkoxy, phenyl; Y=phenyl substituted with H, unsubstituted alkyl, halogen; Xb=piperidinyl substituted at the N-terminal with –Z-A where –Z- is unsubstituted methylene (-CH2-) or substituted with unsubstituted alkyl and –A is pyridinyl substituted with H, alkyl, halogen, alkoxy, haloalkylalkoxy, -S alkyl, -NHalkyl, and R1 (of Xb)= pyridinyl substituted with H, thienyl, -Salkyl, halogen and alkyl; thiazolyl substituted with H and alkyl; cyano; -CO2alkyl substituted with H, alkyl, phenyl; and imidazolyl and compositions thereof classified in class 546, subclass 208 and class 514, subclass 318. A further election of a single disclosed species is required.

III. Claims 1-8, 11-26 and 28 are drawn to compounds of Formula B that are not encompassed by Groups I or II that can be classified in class 540, 544, 546 and 548, subclass dependent upon species elected. A further election of a single disclosed species is required. This group may be subject to further restriction.

IV. Claim 9 is drawn to a method of regulating function of a neuromedin U receptor limited to the scope of one of Groups I-III, classified in class 514, dependent on the species elected. An election of a single disclosed species for use in this method is also required.

V. Claim 27 is drawn to a prodrug of Formula B limited to the scope of Groups I, II or III that can be classified in class 546, subclass variable and dependent upon species elected. A further election of a single disclosed species is required.

**Note:** Claim 28 is claims a medicine and for restriction purposes will be considered as a composition.

Some composition claims include functional language. Regardless of function language, these claims are considered to only be composition claims.

The inventions are distinct, each from the other because of the following reasons:

Groups I – III are independent and distinct from each other as they are drawn to compounds of formula B and I" with different divergent moieties in the R1, R2, A, B, Z, D, Q1, Q2, X and Y positions. Group I requires compounds and compositions of Formula B, wherein Q2=-COR2 where R2 is unsubstituted alkyl, haloalkyl, unsubstituted alkoxy, phenyl; Y=phenyl substituted with H, unsubstituted alkyl, halogen; Xb=piperidinyl substituted at the N-terminal with –Z-A where –Z- is unsubstituted methylene (-CH2-) or substituted with unsubstituted alkyl and –A is phenyl substituted with H, alkyl, halogen, alkoxy, haloalkylalkoxy, -S alkyl, -NHalkyl, and R1 (of Xb)= pyridinyl substituted with H, thienyl, -Salkyl, halogen and alkyl; thiazolyl substituted with H and alkyl; cyano; -CO2alkyl substituted with H, alkyl, phenyl; and imidazolyl. Group II requires compounds and compositions of Formula B, wherein Q2=-COR2 where R2 is unsubstituted alkyl, haloalkyl, unsubstituted alkoxy, phenyl; Y=phenyl substituted with H,

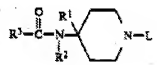
unsubstituted alkyl, halogen; Xb=piperidinyl substituted at the N-terminal with –Z-A where –Z- is unsubstituted methylene (-CH2-) or substituted with unsubstituted alkyl and –A is pyridinyl substituted with H, alkyl, halogen, alkoxy, haloalkylalkoxy, -S alkyl, -NHalkyl, and R1 (of Xb)= pyridinyl substituted with H, thienyl, -Salkyl, halogen and alkyl; thiazolyl substituted with H and alkyl; cyano; -CO2alkyl substituted with H, alkyl, phenyl; and imidazolyl. Group III requires all compounds and composition of formula B that are not encompassed by Groups I and II. Group V requires prodrugs of Formula B limited to the scope of Groups I, II or III.

The compounds of group V do not fall within groups I – III. Each of groups I - III and V are directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. Each of groups I – III and V have different classifications and subclasses. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been

expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in groups I - III and V, these inventions are distinct.

Inventions (I – III and V) and (IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case Groups I – III and V are drawn to compounds, compositions, and prodrugs. Group IV is drawn to a method of treatment of regulating function of a neuromedin U receptor limited to the scope of one of Groups I-III.

The method of treatment can be practiced with another materially different product. For example, Lin et al discloses compounds of that falls within the scope of claimed compounds (see US 4,791,120). This is just one method of treatment.



where $R^1$ is an unsubstituted or substituted heterocyclic ring system; $R^2$ is an unsubstituted or substituted phenyl; $R^3$ is a lower alkyl or lower alkoxy, and L is selected from a wide variety of groups.

Because these inventions are distinct for the reasons given above and the search required for group I is not required for groups II – V, restriction for examination purposes as indicated is proper. Groups I - V are not identically classified under U.S. Patent Classification guidelines, thus, to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. Thus, groups I - V have been appropriately restricted on the basis of being both independent or distinct and presenting an unduly search burden on the Examiner if they were to be searched together.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Rejoinder Advisory***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625
3/11/08